REMARKS

Claims 1-8 are pending in the subject application. In the Office Action of November 13, 2007, claims 1-8 stand rejected. Claims 1-8 have been amended to correct matters of form. New claims 9-18 have been added. New claims 9-18 find support throughout the specification. For example, new claims 9, 10 and 15 find support on page 5, paragraphs 3-4, of the specification and in the Summary on pages 2-3. New claims 11-14, and 16-18 find support, for example, in the original claims. It is submitted that no new matter has been introduced by the amendment or addition to the claims.

A. Rejection of Claims 1 and 6-8 under 35 U.S.C. §103(a)

Claims 1 and 6-8 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over U.S. Patent No. 3,893,843 to Fry et al. (hereinafter "Fry") in view of U.S. Patent No. 5,961,921 to Addy et al. (hereinafter "Addy"). Applicants traverse this rejection for at least the reasons set forth herein.

As set forth in MPEP §2142, the key to supporting any rejection under 35 U.S.C. §103(a) is the clear articulation of the reason why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. §103(a) should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

As further set forth in MPEP §2143, to establish a *prima facie* case of obviousness, the Examiner must articulate a rationale for the rejection. Applicants assert that the disclosures in Fry and Addy provide no teaching, suggestion, or motivation to one of ordinary skill to combine these reference teachings to arrive at the claimed invention. *See* MPEP §2143 (Eighth edition, revision 6, September 2007).

A rejection under §103(a) based on this rationale requires that three basic findings be made:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings in the manner asserted;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. *See* MPEP §2143.

In this matter, *i.e.*, where the Examiner contends that the claimed invention is obvious because of a combination of elements gleaned from the reference teachings, the Examiner must explain why it would have been obvious to one of ordinary skill in the art to make the asserted combination. Applicants respectfully submit that there is no reason why one or ordinary skill in the art would arrive at the subject matter recited in claim 1 in view of the combination of teachings of Fry and Addy because modifying Fry to incorporate the vaporization step of Addy would change the principle of operation of the system and method in Fry in a manner that is neither suggested or contemplated by Fry. Furthermore, it is submitted that Fry teaches away from modifications that involve vaporization techniques, as recited in claims 1 and 6-8.

Independent claim 1 and the claims that depend therefrom, recite, "[a] method

for cleaning and sterilizing a medical device comprising: placing the device into a container; cleaning the device in the container with a cleaning solution; rinsing the device in the container with a rinse solution; vaporizing a liquid substance in the container to create a sterilant vapor; and contacting the device with the vapor to effect sterilization of the device."

Fry discloses a single decontaminating unit that automatically washes and disinfects hollow articles using cold liquid disinfectant. The articles are first washed free of solid contaminants, rinsed, and then disinfected by immersing the articles in a chemical disinfecting solution without the application of heat. Fry teaches that it is "highly important" that the tub and hollow articles to be decontaminated be completely emptied of any washing or rinsing liquid prior to placing disinfectant in the tub, and that the disinfectant in the tub be effectively removed from each of the articles and the tub at the end of the disinfecting cycle (col 2, lines 48-68). Fry accomplishes "complete" removal of residual traces of washing, rinsing, or disinfecting solution through a high speed centrifugal technique (col. 3, lines 15-57).

As acknowledged by the Examiner, "Fry does not disclose vaporizing a liquid substance in the container to create a sterilant vapor and contacting the device with the vapor to effect sterilization of the device." (Office Action, page 3, first paragraph). Applicants agree. In fact, a stated objective of Fry is to avoid normal heat sterilizing equipment, as the method disclosed by Fry is directed to disinfecting hospital anesthesia and inhalation therapy items that are made of heat-sensitive material such as natural or synthetic rubber, plastic, or the like (col. 1, lines 33-37). Furthermore, there is nothing in Fry that would suggest that the Fry apparatus can accommodate or

withstand the low pressures necessary for vaporizing liquid within the container to create a sterilant vapor, as recited in claims 1 and 6-8.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *See* MPEP §2141.02(VI). In fact, it has been held that an important indicator of non-obvious is "teaching away" from the claimed invention by the prior art or known by those of ordinary skill. *See U.S. v. Adams*, 383 US 39, 148 USPQ 479 (1966). Indeed, express teaching away from the claimed invention is a *per se* demonstration of lack of *prima facie* obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525 (Fed. Cir. 1987).

Fry clearly teaches a cleaning and sterilizing method that employs a single contaminating unit which automatically washes and disinfects hollow articles of the type described using cold liquid disinfectant, without the use of heat (col. 2, lines 3-13). Thus, Fry clearly states that normal heat sterilizing equipment is not suitable in the Fry process (col. 1, lines 33-41). Therefore, it is clear that Fry does not, and would not, include a vapor sterilization step that employs heat. Furthermore, there is no teaching in Fry that would suggest that the Fry apparatus can accommodate low pressures necessary to vaporize a liquid within the chamber, or to withstand low negative pressure necessary to vaporize liquid sterilant. Indeed, it is submitted that the Fry apparatus is not configured to do so. The present specification at pages 6-30 provides a detailed discussion of embodiments that employ negative pressure to vaporize liquid sterilant, focusing on, for example, the specialized equipment and processing steps that are

necessary to do so. In contrast, Fry mentions the word "pressure" only 5 times throughout the specification: twice when referring to the liquid transfer system (beginning at col. 10, line 37); twice to discuss the parts within the retaining screen 217 (col. 16, lines 35-46); and once to discuss water pressure (col. 17, line 20). Accordingly, it is submitted that Fry does not contemplate, and is not configured for, negative pressure vaporization systems.

Even if, *arguendo*, Fry could accommodate low vaporization pressures, Fry teaches that it is "highly important" that the washing, rinsing, and disinfectant solutions be completely emptied and not "trapped in the common parts of the system" following each successive cycle to avoid decontamination (col. 2, lines 48-68). Thus, one of ordinary skill in the art reading Fry would understand that no liquid solution remains between the Fry cycles that could be used for purposes of vaporizing a liquid substance in the container to create a sterilant vapor, as recited in claim 1 and 6-8.

Accordingly, it is respectfully submitted that Fry teaches away from vaporizing a liquid substance in the container to create a sterilant vapor for at least three reasons: 1) Fry teaches that the use of heat is to be avoided; 2) Fry does not contemplate and is not configured for low vaporization pressure processes; and/or 3) Fry teaches that it is highly important that all residual liquid solutions be removed from the process between each successive cycle.

Addy provides no teaching that when combined with Fry that would render obvious claim 1. Addy discloses methods of peroxide vapor sterilization of medical devices. Indeed, one of ordinary skill in the art reading Addy would not combine the

teachings of Addy to those of Fry, because Addy, in many important aspects, teaches a process that is directly opposite the Fry process.

It has been held that "if a proposal for modifying the prior art in an effort to attain the claimed invention causes the art to become inoperable or destroys its intended function, then the requisite motivation to make the modification would not have existed." See *In re Fritch*, 972 F.2d at 1265, 23 USPQ.2d at 1783. Furthermore, MPEP §2143.01 (VI) states "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

It is submitted that it would be improper to combine the Fry and Addy references because the combination or modification of the Fry process to vaporize a liquid substance in the container to create a sterilant vapor, as suggested by the Examiner, would destroy the intended function and/or the method of Fry. For example, as set forth herein, the method of Fry was designed to disinfect hospital anesthesia and inhalation therapy items that are made of heat-sensitive material such as natural or synthetic rubber, plastic, or the like (col. 1, lines 33-37). Accordingly, Fry teaches the use of cold, liquid disinfectant (col. 2, lines 3-13). Fry's principle intended function would be changed or destroyed if the Fry method incorporated vapor sterilization, as taught by Addy. Indeed, combining the "vapor sterilization" step of Addy with the method of cleaning and sterilizing a medical device of Fry would require wholesale modifications of function and operation in a manner that is neither contemplated nor intended by Fry. Indeed, because Fry teaches the importance of removing all residual liquid solutions in

the process between each successive cycle, there would be no liquid solution after a cycle to vaporize that liquid in the container, as recited in claims 1-8. It is respectfully submitted that a process that retained liquid in the container for the purposes of vaporization would be directly opposite the intended teachings and function of Fry.

Thus, it is respectfully submitted that a *prima facie* case of obviousness for claims 1 and 6-8 in view of the combination of teachings of Fry further in view of Addy has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 1 and 6-8 under 35 U.S.C. §103(a) in view of Fry further in view of Addy.

B. Rejection of Claim 2 under 35 U.S.C. §103(a)

Previous claim 2 was rejected under 35 U.S.C. §103(a) for assertedly being unpatentable over Fry in view of Addy further in view of U.S. Patent No. 5,711,921 to Langford et al. (hereinafter "Langford"). Applicants traverse this rejection for at least the reasons set forth herein.

As discussed in *Section A*, herein, the combination of Fry in view of Addy is clearly distinguished from claim 1 and the claims that depend therefrom (*i.e.* claim 2). Furthermore, Langford when combined with Fry in view of Addy provides no teaching that would render obvious claim 2. Indeed, the Examiner only cites Langford for the teaching of a method comprising storing a device in a container in sterile form.

Accordingly, Applicants respectfully request the withdrawal of the rejection of claim 2 under 35 U.S.C. §103(a) in view of Fry in view of Addy further in view of Langford.

C. Rejection of Claim 3 under 35 U.S.C. §103(a)

Previous claim 3 was rejected under 35 U.S.C. §103(a) for assertedly being unpatentable over Fry in view of Addy further in view of U.S. Patent No. 5,882,589 to Mariotti et al. (hereinafter "Mariotti"). Applicants traverse this rejection for at least the reasons set forth herein.

As discussed in *Section A*, herein, the combination of Fry in view of Addy is clearly distinguished from claim 1 and the claims that depend therefrom (*i.e.* claim 3). Furthermore, Mariotti when combined with Fry in view of Addy provides no teaching that would render obvious claim 3. Indeed, the Examiner only cites Mariotti for the teaching of one of the method steps including a disinfectant comprising a retained portion of a rinse solution.

Accordingly, Applicants respectfully request the withdrawal of the rejection of claim 3 under 35 U.S.C. §103(a) in view of Fry in view of Addy further in view of Mariotti.

D. Rejection of Claims 4-5 under 35 U.S.C. §103(a)

Previous claims 4-5 were rejected under 35 U.S.C. §103(a) for assertedly being unpatentable over Fry in view of Addy further in view of U.S. Patent No. 4,917,123 to McConnell et al. (hereinafter "McConnell"). Applicants traverse this rejection for at least the reasons set forth herein.

As discussed in *Section A*, herein, the combination of Fry in view of Addy is clearly distinguished from claim 1 and the claims that depend therefrom (*i.e.* claims 4-5).

Furthermore, McConnell when combined with Fry in view of Addy provides no teaching that would render obvious claims 4-5. Indeed, the Examiner only cites McConnell for the teaching of a rinse solution comprising a chemical sterilant such as hydrogen peroxide.

Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 4-5 under 35 U.S.C. §103(a) in view of Fry in view of Addy further in view of McConnell.

E. New Claims 9-18

Claims 9-18 have been added to the instant application and are believed to be patentable for at least the reasons set forth herein.

In particular, new claims 9-18 recite a method of cleaning and sterilizing a medical device that comprises retaining a predetermined amount of a liquid substance in the container prior to the vaporizing. As discussed throughout the specification, in certain embodiments, the subject application teaches a process wherein a known volume of liquid substance remains in, for example, a well so that a subsequent vaporization process can be performed on the device with a known volume of liquid (for example, Summary and page 5, lines 21).

As discussed above, Fry teaches a method of cleaning and sterilizing a medical device. Addy teaches a method for peroxide vapor sterilization. However, Fry in view of Addy does not teach a method of cleaning and sterilizing a medical device comprising: retaining a predetermined amount of the liquid substance, such as a liquid sterilant, in the container and vaporizing the liquid substance in the container to create a

vapor to sterilize the device, as recited in claims 9-18. Indeed, as discussed herein, Fry teaches "complete" removal of residual traces of washing, rinsing, or disinfecting solution through a high speed centrifugal technique.

Thus, Applicants respectfully submit that claims 9-18 are allowable in view of the prior art of record.

F. Status of Related Applications

This application is a continuation-in-part-of U.S. Application Serial No. 09/746,106, filed December 22, 200, now U.S. Patent 6,656,427, which is a continuation-in-part of U.S. Patent No. 6,203,756. Pending U.S. Application No. 11/024,118 ("the '118 application"), filed December 28, 2004, claims the benefit of the present application. In the '118 application, a Response to a non-final Office Action was entered and forwarded to the Examiner on May 5, 2008.

CONCLUSION

Applicants respectfully submit that claims 1-18 recite novel and non-obvious methods for cleaning and sterilizing a medical device. Applicants believe that these claims define over the prior art of record and are in proper form for allowance. In view of the foregoing, Applicants respectfully submit that the subject application is in condition for allowance. Accordingly, reconsideration of the rejections to claims 1-8 and allowance of all claims 1-18 at an early date are earnestly solicited.

Applicants do not otherwise concede, however, the correctness of the rejections with respect to any of the dependent claims not discussed above. Accordingly, Applicants hereby reserve the right to make additional arguments as may be necessary to further distinguish the dependent claims from the cited references based on additional features contained in the dependent claims that were not discussed above. A detailed discussion of these differences is believed to be unnecessary at this time in view of the differences in the claims pointed out above.

Applicants submit that the enclosed fee necessary for consideration of this Response is sufficient. Nevertheless, the Commissioner is hereby authorized to charge any additionally required fees deemed necessary for consideration of this Response to Account No. 11-1110.

If the undersigned can be of assistance to the Examiner in addressing any additional issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,

May 13, 2008
Date

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